K002920

DEC 1 8 2000

510(K) Summary

Escalon Medical Imaging CFA Digital Imaging System

Name of Device: CFA Digital Imaging System

Common or usual name: Camera, Ophthalmic (AC Powered)

Classification Name: Ophthalmic Camera (per 21CFR.866.1120)

Product Code: HKI

Submitter: Escalon Medical Corporation
2440 South 179th Street
New Berlin, WI 53146
Phone: 800-433-8197
Facsimile: 262-821-9927
Contact Person: Ron Hueneke
Date Prepared: September 14, 2000
(revised December 14, 2000)

Predicate Devices

Trade Name	Manufacturer	510(k)
Imagescope Digital Retinal Imaging System	Tomey Corporation	K971685
Imagenet Digital Ophthalmic Imaging System	Topcon	K870039
Digiscope Ophthalmic Camera	Eyetel Imaging Inc.	K990205

Intended Use

The Escalon Medical Imaging CFA Digital Imaging System, Tomey Corporation Image Scope Digital Retinal Image System, Topcon, Inc. ImageNet Digital Imaging System and the EyeTel Digiscope are intended to capture images of the retina taken by a fundus camera. The Escalon imaging system is an automated imaging device used in conjunction with the users fundus camera and is intended to capture and store images of the fundus. The Escalon Imaging System require minimal operator training and intervention during the imaging process. It is indicated for individuals where examination of the fundus for pathologies is requested. The predicate devices are likewise comprised of fundus cameras and computer hardware and software systems intended to capture and store images of the fundus. Thus the Escalon Medical Imaging CFA Digital Imaging System has the same intended use and indication as these predicate devices.

Substantial Equivalence

Escalon Medical Imaging's CFA Digital Imaging System, The Tomey Corporation's Image Scope, Topcon's ImageNet System, and Eyetel's Digiscope have the same intended use: to capture and store images of the fundus. The CFA Digital

Imaging System and the predicate devices have similar principles of operation and technological characteristics. Each of the devices is an ophthalmic camera. The user views the patient's retina through a fundus camera. A light sources is used to generate images of the retina which are captured by the digital camera. The images are then digitized and stored. Successive images are taken to permit viewing of a larger area of the retina.

The technological differences between the Escalon Medical Imaging CFA Digital Imaging System and its' predicate devices are the higher resolution of the images due to a physically larger digital chip than any other system, and the media on which the images are captured. However these differences do not raise any new question of safety or efficacy of the system. In each device, the data is acquired in a non compressed format and is capable of being stored in individual image files. The minor difference in data storage is an uncompressed state on the hard drive of the computer system. The Imagescope System permits the downloading of the data with compression to a gigabyte JAZ drive and The Topcon ImageNet utilizes a read and write CD-Rom recorder to store the images.

Performance Characteristics

The Escalon Medical Imaging CFA Digital Imaging System is comprised of the following components: The Digital Sensor head (CFA Digital Camera Back), a computer interface circuit board (CFA/Omni Board), and a Connecting cable (CFA/Omni Cable). These components, combined and sold together with the EyePhoto Software and computer system with image acquisition and hardware control capabilities, are used in conjunction with a fundus camera to take digital pictures of the retina which are then transferred via the CFA Digital Camera back and connecting cable to the computer system where they may be viewed, modified and printed. The CFA Digital Imaging System is intended to capture and store images of the fundus, and it is also indicated for use as an ophthalmic camera for individuals where examination of the fundus have been requested for pathologies.

The CFA Digital Imaging System's user software interface will allow the images of the fundus to be acquired, monitored stored and also retrieved. Imaging, focusing and camera orientation in relation to the retina are controlled by the user. With verification and monitoring being done by the user the software allows the user to monitor, capture , process, and verify that the device is operating correctly. The image of the fundus is acquired by the CFA Digital Imaging System and then can be stored in individual image data files which are in a non compressed state on the hard drive of the computer system and will be display electronically.

Conclusion

Escalon Medical Imagings' CFA Digital Imaging System has the same intended use indications and very similar principles of operation to the predicate devices. It also has very similar technological characteristics as the Tomey Corporation's Image Scope Digital Retinal Image System, Topcon's ImageNet Digital Imaging System, and Eyetel

Imagings' Digiscope Ophthalmic Camera. The minor differences between the CFA Digital Imaging System and the predicate devices do not raise any new questions of safety or the effectiveness of the system. Thus, the Escalon Medical Imaging CFA Digital Imaging System is substantially equivalent to legally marketed ophthalmic camera systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2000

Mr. Ron Hueneke
Escalon Medical Corporation
2440 South 179th Street
New Berlin, WI 53146

Re: K002920
Trade Name: CFA Digital Imaging System
Regulatory Class: II
Product Code: 86 HKI
Regulation: 886.1120
Dated: September 14, 2000
Received: September 19, 2000

Dear Mr. Hueneke:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002920

Device Name: CFA Digital Imaging System

Indications For Use:

The Escalon Medical Imaging CFA Digital Imaging System is a replacement camera back for the 35mm film camera back on the Zeiss FF3, Zeiss FF4 and TopCon 50X/IA used to capture and store images of the fundus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use MRB/1
(Per 21 CFR 801.109)

Marsha L. Burke Nicholas
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002920